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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/425,742	10/22/1999	KARL THEODOR KRAEMER	02481.1641	9957

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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1619

DATE MAILED: 12/21/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 09/425,742	Applicant(s) KRAEMER ET AL.	
	Examiner Lauren Q Wells	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claims 1-29 are pending. Claim 9 is withdrawn from consideration, as it is directed toward non-elected subject matter.

CLARIFICATION OF RECORD

This communication is necessary to clarify the record. Specifically, the finality of the Office Action mailed September 17, 2001, Paper No. 13, is hereby withdrawn. In the Office Action mailed September 17, 2001 and the Office Action mailed May 16, 2001, Paper No. 7, the Examiner failed to include Cretois (5,558,859) in the heading of the 35 USC 103(a) rejection. Thus, a non-final action on the merits is as follows.

The Examiner respectfully notes, though, that a PTO-892 was mailed with the Office Action of September 17, 2001, Paper No. 13, citing the Cretois (5,558,859) reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 and 10-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claussner et al. (6,087,509) or Claussner et al. (5,750,553) in view of Cretois (5,558,859) in

Art Unit: 1619

further view of Lai (5,916,910), Ismail (5,541,220), Galey et al. (WO 9221317), Dumats et al. (WO 9119701), and Estradier et al. (EP 427625).

Claussner et al. ('509) teach (Col. 5, lines 59-60) 4-(3-(4-hydroxy-2-butyn-1-yl)-4,4-dimethyl-2,5-dioxo-1-imidazolidinyl)-2-(trifluoromethyl)-benzonitrile, 4-(4,4-bis(fluoromethyl)-2,5-dioxo-3-(2-fluoroethyl)-1-imidazolidinyl)-2-(trifluoromethyl)-benzonitrile, 4-(2,5-dioxo-4,4-bis(fluoromethyl)-3-(4-hydroxy-2-butyn-1-yl)-1-imidazolidinyl)-2-(trifluoromethyl)-benzonitrile, and 4-[2,4-dioxo-1-(4-hydroxybutyl)-1,3-diazospiro[4.5]decan-3-yl]-2-(trifluoromethyl)-benzonitrile and all possible racemic, enantiomeric and diastereoisomeric isomer forms as a medicament of formula (I), where formula (I) is a 1-imidazolidinyl-phenyl that is used (Col. 9, lines 35-46) for the treatment of cutaneous affections such as acne, hyperseborrhea, alopecia or hirsutism. See entire disclosure.

Claussner et al. ('553) teach optionally substituted phenylimidazolidines and the pharmaceutical compositions containing them, their preparation process, and their use as medicaments. Claussner et al. teach (Col. 1, lines 24-50) an imidazolidine of general formula (I). Claussner et al. teach that Z_1 and Z_2 , which correspond to R_1 and R_2 of the instant invention, may be identical or different. Claussner et al. teach that Z_1 and Z_2 may be a cyano or a trifluoromethyl radical. Claussner et al. teach -A-B-, corresponding to "X" and "Y" of the instant invention, as an amide. Claussner et al. teach R_3 , corresponding to R_4 of the instant invention, as being chosen from the following radicals: a hydrogen atom; alkyl, alkenyl, alkynyl, aryl or arylalkyl radicals having at most 12 carbon atoms, these radicals being optionally substituted by one or more substituents chosen from halogen atoms and other radicals, such as hydroxy and hydroxyalkyl. Claussner et al teach (Col. 2, lines 9-10) R_4 and R_5 as identical or

Art Unit: 1619

different and representing a hydrogen atom or an alkyl radical having 1-12 carbon atoms.

Claussner et al. teach (Col. 3, line 14-17) formula (I) in all possible racemic, enantiomeric and diastereoisomeric isomer forms, as well as the addition of salts. Claussner et al. teach (Col. 13, lines 58-60) formula (I) for the use as medicaments for (Col. 14 lines 1-2) the treatment of cutaneous affections such as acne, hyperseborrhea, alopecia or hirsutism. Claussner et al teach (Col. 14, lines 6-8) formula (I) can be used in combination with an inhibitor of 5α -reductase such as (5α 17 β)-1,1-dimethylethyl3-oxo 4-aza-androst-1-ene 17-carboxamide for the treatment of acne, alopecia or hirsutism, which meets claims 11, 16, and 17. Claussner et al. teach (Col. 14, lines 10-11) that formula (I) can also be combined with a product stimulating hair growth such as Minoxidil for the treatment of alopecia.

Claussner and Claussner fail to teach preferred film forming agents, solvents, plasticizers and additives.

Cretois teaches compositions for the treatment and protection of the exoskeletal parts, such as hair and skin, based on ceramides and vinylpyrrolidone polymers. Cosmetic compositions comprising Luviquat® FC 905 (copolymer of vinylimidazolium methochloride and vinyl pyrrolidone) and Cremophor® RH 410 (polyethoxylated hydrogenated castor oil). Cosmetically acceptable mediums disclosed include water and monoalcohols, such as ethanol and isopropanol. See Col. 1, line 6-Col. 2, line 11; Col. 4, line 43-Col. 12, line 16.

Lai teaches pharmacologically active agents and their uses. Lai teaches (Col. 3, lines 49-51) an agent that can be used to reduce cutaneous irritation and alopecia. Lai teaches (Col. 8, lines 51-54) captopril, fosinopril, and calcium channel blocking agents such as diltiazem,

Art Unit: 1619

felodipine, nicardipine, nifedipine as pharmacologically active agents, which meets claims 11-14.

Ismail teaches agents for the treatment and protection of skin. Ismail teaches (Col. 8, example 24) pentoxifyllin as a component of a capsule used for treatment for conditions such as alopecia, which meets claims 11 and 15.

Estradier et al. teach salts of 2,4-diamino-alkoxy 3-sulph-oxy pyrimidinium hydroxide used in cosmetic compositions for preventing hair loss or promoting hair re-growth. Estradier et al. teach 2,4-diamino 6-(m-butyloxy) 3-sulphoxy pyridinium hydroxide, which meets claims 11, 18, and 19.

Galey et al. teach compositions containing pyridine-1-oxide derivatives for combating hair loss and stimulating hair growth. Galey et al. teach 2,6-diamino-4-piperidinopyridine, which meets claims 11, 13, and 20.

Dumats et al. teach 2,4-diamino triazine oxides(s) for prevention and treatment of hair loss. Dumats et al. teach 2,6-diamino-4-butoxy-2,3,5-triazine 1-oxide, which meets claims 11, 18 and 20.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the compositions of Claussner et al. or Claussner et al. using the teachings of Cretois and obtain a composition comprising formula (I), vinylimidazolium methochloride/vinylpyrrolidone copolymer, polyethoxylated hydrogenated castor oil, and solvent because a) Cretois, Claussner, and Claussner teach cosmetic compositions for the treatment and protection of the exoskeletal parts of the body; b) Cretois teaches antiseborrhoic agents for use in the composition and Cretois teaches these antiseborrhoic agents in composition with

Art Unit: 1619

vinylimidazolium methochloride/vinylpyrrolidone copolymers, polyethoxylated hydrogenated castor oil, and solvent; c) Claussner et al. and Claussner et al. teach compositions comprising formula (1) for the treatment of hyperseborrhea; d) Claussner et al. and Claussner et al. teach that the active ingredient, formula (1), can be incorporated with aqueous vehicles and dispersing or emulsifying agents; e) Cretois teaches dispersing or emulsifying agents. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of the combined references using the teachings of Lai, Ismail, Estradier et al., Galey et al., Dumats et al. and obtain a composition further comprising promoters of hair growth because a) Claussner et al. and Claussner et al. teach that the composition can also be combined with a product stimulating hair growth for the treatment of alopecia; b) Lai, Ismail, Estradier et al., Galey et al., and Dumats et al. all teach compounds for the stimulation of hair growth.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.


Application/Control Number: 09/425,742

Page 7

Art Unit: 1619

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
December 11, 2001



DAMERON L. JONES
PRIMARY EXAMINER